

CLAIMS

What is claimed is:

1. A lactoferrin composition comprising an N-terminal lactoferrin variant.
2. The lactoferrin composition of claim 1, wherein said lactoferrin is recombinant lactoferrin.
3. The lactoferrin composition of claim 1, wherein said N-terminal lactoferrin variant lacks at least the N-terminal glycine residue.
4. The composition of claim 1, wherein said N-terminal lactoferrin variant comprises at least 1% to at least 50% of the lactoferrin composition.
5. A pharmaceutical composition comprising a therapeutically effective amount of a lactoferrin composition and a pharmaceutically acceptable polymer having a viscosity in the range of about 1 to about 12,000,000 cP at room temperature.
6. The composition of claim 5, wherein said lactoferrin is mammalian lactoferrin.
7. The composition of claim 5, wherein said lactoferrin is recombinant lactoferrin.
8. The composition of claim 5, wherein said lactoferrin is an N-terminal lactoferrin variant.
9. The composition of claim 8, wherein said N-terminal lactoferrin variant comprises at least 1% to at least 50% of the lactoferrin composition.
10. The composition of claim 5, wherein the polymer is selected from the group consisting of vinyl polymer, polysaccharide polymer, glycosaminoglycan polymer, protein polymer, polyoxyethylene-polyoxypropylene polymer and acrylamide polymer.
11. The composition of claim 10, wherein the polyoxyethylene-polyoxypropylene polymer is a polyoxyethylene-polyoxypropylene block copolymer.
12. The composition of claim 11, wherein the polyoxyethylene-polyoxypropylene block copolymer is F88 or F127.

13. The composition of claim 5, wherein the lactoferrin concentration is within the range of about 0.0001% (w/w) to about 30% (w/w).
14. The composition of claim 10, wherein the polymer concentration is about 0.5% (w/w) to about 3.0% (w/w) and the polymer has an average molecular weight of about 500 to about 13,000,000.
15. A method for treating a wound in a subject comprising the step of contacting the wound with the composition of claim 5.
16. A method of treating a wound comprising the step of administering to a subject a therapeutically effective amount of a lactoferrin composition in
17. The method of claim 16, wherein said lactoferrin composition is administered topically, orally or parenterally.
18. The method of claim 17, wherein said lactoferrin composition is administered orally.
19. The method of claim 18 further comprising administering an antacid in conjunction with said lactoferrin composition.
20. The method of claim 16 further comprising administering a standard wound healing therapy in combination with the lactoferrin composition.
21. The method of claim 16, wherein the administering comprises administering said composition for at least one week to at least twelve weeks.
22. The method of claim 16, wherein the amount of the lactoferrin that is administered is about 0.0001 μg to about 100 g per day.
23. The method of claim 16, wherein said composition is a topical gel, a solution, capsule or a tablet having a lactoferrin concentration of about 0.0001% to about 30%.
24. The method of claim 23, wherein said topical gel is composed from a polymer selected from the group of consisting of a vinyl polymer, polysaccharide polymer, glycosaminoglycan polymer, protein polymer, polyoxyethylene-polyoxypropylene polymer, and acrylamide polymer.

25. The method of claim 24, wherein the polymer concentration is about 0.5% (w/w) to about 3.0% (w/w) and the polymer has a molecular weight of about 50,000 to about 13,000,000.
26. The method of claim 16, wherein the wound is selected from the group consisting of skin wound, bone wound, internal wound, gastrointestinal wound, oral wound, ophthalmic wound, and surgical wound.
27. The method of claim 26, wherein the wound is further defined as a chronic wound.
28. The method of claim 26, wherein the wound is further defined as an acute wound.
29. The method of claim 27, wherein the chronic wound is selected from the group consisting of diabetic ulcer, venous stasis ulcer, pressure ulcer, and infected wound.
30. The method of claim 28, wherein the acute wound is selected from the group consisting of first degree burn, partial-thickness burn, full-thickness burn, laceration, bullet wound, and infected wound.
31. A method of treating a wound comprising the step of supplementing the local immune system in a subject by administering topically an amount of a lactoferrin composition in the vicinity of the wound.
32. The method of claim 31, wherein the lactoferrin results in the killing of bacteria infecting the wound.
33. A method of enhancing the local immune system in a subject suffering from a wound comprising the step of administering topically to the subject a lactoferrin composition.
34. The method of claim 33, wherein the lactoferrin composition stimulates the production of a cytokine or a chemokine.
35. The method of claim 33, wherein the lactoferrin composition results in an inhibition of a cytokine or a chemokine.
36. The method of claim 34, wherein the cytokine is selected from the group consisting of interleukin-18 (IL-18), interleukin-12 (IL-12), granulocyte/macrophage colony-stimulating factor (GM-CSF), and gamma interferon (IFN- γ).

37. The method of claim 34, wherein the chemokine is macrophage inflammatory protein 3 alpha (MIP-3 α), macrophage inflammatory protein 1 alpha (MIP-1 α), macrophage inflammatory protein 1 beta (MIP-1 β).
38. The method of claim 35, wherein the cytokine is selected from the group consisting of interleukin-2 (IL-2), interleukin-4 (IL-4), interleukin-5 (IL-5), interleukin-10 (IL-10), and tumor necrosis factor alpha (TNF- α).
39. The method of claim 33, wherein the lactoferrin composition inhibits the production of matrix metalloproteinases (MMPs).
40. The method of claim 36, wherein interleukin-18 or granulocyte/macrophage colony-stimulating factor stimulates the production or activity of immune cells.
41. The method of claim 36, wherein interleukin-18 or granulocyte/macrophage colony-stimulating factor stimulates the production or activity of cells involved in wound repair.
42. The method of claim 40, wherein the immune cells are selected from the group consisting of T lymphocytes, natural killer cells, macrophages, dendritic cells, and polymorphonuclear cells.
43. The method of claim 42, wherein the polymorphonuclear cells are neutrophils.
44. The method of claim 42, wherein the T lymphocytes are selected from the group consisting of CD4+, CD8+ and CD3+ T cells.
45. The method of claim 41, wherein the cells involved in wound repair are selected from the group consisting of keratinocytes, endothelial cells, fibroblasts, dendritic cells and myofibroblasts.
46. The method of claim 38, wherein the inhibition of TNF-alpha further inhibits the migration and maturation of dendritic cells.
47. The method of claim 46, wherein the dendritic cells are Langerhans cells.

48. A method of treating a wound comprising the step of supplementing the systemic immune system in a subject by administering via a parenteral route an amount a lactoferrin composition.
49. A method of enhancing the systemic immune system of a subject suffering from a wound comprising the step of parenterally administering to the subject a lactoferrin composition.
50. A method of treating a wound comprising the step of supplementing the mucosal immune system in a subject by administering orally an amount of a lactoferrin composition.
51. A method of enhancing the mucosal immune system in a subject suffering from a wound comprising orally administering to the subject a lactoferrin composition.